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| 10/576,000      | 01/08/2007  | Xiaobing Wu          | ZLO.102             | 8805             |

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SALIWANCHIK LLOYD & SALIWANCHIK  
A PROFESSIONAL ASSOCIATION  
PO Box 142950  
GAINESVILLE, FL 32614

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| EXAMINER |
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LUCAS, ZACHARIAH

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| ART UNIT | PAPER NUMBER |
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1648

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| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

06/03/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

|                              |                                      |                                  |  |
|------------------------------|--------------------------------------|----------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/576,000 | <b>Applicant(s)</b><br>WU ET AL. |  |
|                              | <b>Examiner</b><br>Zachariah Lucas   | <b>Art Unit</b><br>1648          |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1-3 are pending and under consideration in the application.
2. In the prior action, mailed on February 25, 2010, claims 1-3 were pending, under consideration, and rejected.
3. In the Response of May 20, 2010 the Applicant amended claims 1 and 3.

### ***Specification***

4. **(Prior Objection- Withdrawn)** The disclosure was objected to because of the following informalities: in numerous instances throughout the specification, boxes have been substituted for various other characters. In view of the amendments to the specification, the objection is withdrawn.

### ***Claim Rejections - 35 USC § 112***

5. **(Prior Rejection- Withdrawn)** Claims 1-3 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite as it was not clear what was encompassed by recombinant HSV-1 particles comprising a heterologous sequence "represented by" SEQ ID NO: 1. In view of the amendment of the claims to remove the quoted language, the rejection is withdrawn.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **(Prior Rejection- Maintained)** Claim 1 was rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Conway et al. (J Virol 71:8780-89) and Rabinowitz et al. (J Virol 76:791-801) and of Pitkow et al. (J Neurosci 21:7392-96) and GenBank AF063497. The claims have been amended to limit the claims to recombinant HSV-1 comprising (in the elected embodiment) SEQ ID NO: 1.

The Applicant traverses the rejection on the basis that there would be no motivation to combine the various elements of the claimed invention. The argument is not found persuasive, the combination of the AAV2rep sequence with the AAV1 cap sequence was suggested by the teachings of the Rabinowitz reference, as indicated on page 5 of the prior action. The indicated references also identify the AAVrep2 and cap1 sequences found in SEQ ID NO: 1 as indicated on page 5 (second paragraph) of the prior action. While there may not have been a specific reason to select these sequences relative to other AAV rep2 or cap1 sequences known in the art, they would nonetheless have been obvious embodiments of such a combination. It is noted that MPEP section 2144.06 II specifically notes that an “express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious.” Thus, the fact that the art teaches the combination of an AAV rep2 sequence and an AAV cap1 sequence such as claimed, and identifies sequences such as are found in SEQ ID NO: 1 as obvious embodiments of such sequences is adequate to render obvious the combination.

The additional structural organization of SEQ ID NO: 1, such as the position of the restriction sites, would have been obvious as a matter of choice of sequence or positioning or as routine optimization of the desired sequence for expression and incorporation into the vector.

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It is noted that the Applicant asserts that the ligature of the sequences in the claimed vector enhances the packaging efficiency and output of the AAVs, and that neither the specific sequences nor the advantages thereof are taught or suggested. However, it is also noted that there does not appear to be any demonstration that the claimed sequences provides any significant advantages over those of the prior art. While the Applicant has asserted significant advantages, there is no evidence that any unexpected results have been achieved. The assertion is therefore not found persuasive.

For the reasons above, and the reasons of record, the rejection is maintained.

8. **(Prior Rejection- Maintained)** Claim 3 was rejected under 35 U.S.C. 103(a) as being unpatentable over Conway, Rabinowitz, Pitkow, and GenBank AF063497 as applied to claim 1 above, and further in view of the teachings of Preston et al. (U.S. 2002/0028925). No additional arguments were presented with respect to this rejection over those described above. This rejection is therefore maintained for the reasons of record, and for the reasons indicated with respect to the rejection of claim 1 above.

9. **(Prior Rejection- Maintained)** Claim 2 was rejected under 35 U.S.C. 103(a) as being unpatentable over either Conway, Rabinowitz, Pitkow, and GenBank AF063497 as applied to claim 1 above, or Conway, Rabinowitz, Pitkow, GenBank AF063497, and Preston as applied to claim 3 above, and further in view of either of Mullaney et al. (J Gen Virol 70:449-54) or Herold (J Gen Virol 75:1211-22). No additional arguments were presented with respect to this rejection

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over those described above. This rejection is therefore maintained for the reasons of record, and for the reasons indicated with respect to the rejection of claim 1 above.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### ***Conclusion***

11. No claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/  
Primary Examiner, Art Unit 1648